K091482

JUL - 6 2009

Danyang Huayi Medical Equipment & Supply Co., LTD
One Zhenxing Road, Yunyang Economical Development Zone, Danyang, 212300 CHINA
Tele: 86511-86900809; Fax: 86511-86900805

SECTION 5.0: SUMMARY OF SAFETY AND EFFECTIVENESS

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Contact Person	Mr. Jiuguang (Joe) Song, President
Email	songjiuguang@yahoo.com
Sponsor Information	**Danyang Huayi Medical Supply & Equipment Co., LTD**
Address	1 Zhenxing Road, Yunyang Economic Development Zone Danyang, Jiangsu Province CHINA 212300
Contact person	Mr. Tommy Tang, Manager
Tele	86.511.86900879
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Email	Tomy8034@gmail.com
Date Prepared	**May 10, 2009**
Trade Name	Huayi Lightweight Wheelchair Model: K3, K4
Common/Usual Name	Mechanical wheelchair
Classification Name	Wheelchair, mechanical
Classification Number	890 3850
Classification Panel	Physical Medicine device
CDRH Code	IOR
Regulatory Classification	Class I

5.1: Product Description

The Danyang Huayi K3/k4 wheelchair is a lightweight wheelchair that provides mobility to persons limited to a sitting position. It consists of rigid, mechanical, steel and aluminum frame and nylon upholstery back and seat that meet ISO 7176-16: Resistance to ignition of Upholstered parts. It has two 24" rear wheels and two 8" front casters for turning and maneuverability. The Danyang Huayi K3/K4 wheelchair is intended for the use in indoors and outdoors, over smooth surface (all standard indoor flooring surfaces, concrete, asphalt and pocked dirt) that free of large obstacles and inclines greater than 9 degrees.

5.2 Indication for Use

The Danyang Huayi K3/K4 wheelchair is indicated for providing mobility to persons limited to a sitting position.

5.3 Conformance to Standards

The Danyang Huayi K3/K4 wheelchair production meets the following standards:

- ISO 7176-1 Wheelchair: Determination of static stability
- ISO 7176-3 Wheelchair: Determination of efficiency of brakes.
- ISO 7176-5: Determination of overall dimension, mass and turning space.
- ISO 7176-7: Measurement of seating and wheel dimensions.
- ISO 7176-8 Wheelchair: Requirements and test methods for static, impact and fatigue strengths.
- ISO 7176-11 Wheelchair: Test dummies
- ISO 7176-13: Determination of friction of test surface.
- ISO 7171-15 Wheelchair: Requirements for information disclosure, documentation and labeling.
- ISO 7171-16 Wheelchair: Resistance to ignition of upholstered parts – requirements and test methods.
- ISO 10993-5-1999: Biological Evaluation of Medical Devices – Part 5: Test for *in vitro* Cytotoxicity.
- ASTM D751:89 Section 11 – Procedure A - Tensile Strength
- Section A, Part I and Section D, Part II of California Technical Bullentin 117 Requirements,, Test Procedure and Apparatus for Testing the Flame Retardance of Resilient Filling Materials Used in Upholstered Furniture.
- PVC leather/Nylon fabric/liner in accordance with: Section E part 1 of California Technical Bullentin 117 Requirement, Test Procedure and Apparatus for Testing the Flame Retrardance of Resilient Filling Materials Used in Upholstered Furniture.

5.4 Predicated Device: American Bantex R07-16/18 Wheelchair (K915262)

5.5 Substantial Equivalence

The Danyang Huayi K3/K4 lightweight wheelchair and American BantexRo7-16/18 Wheelchair (K915262) are substantially equivalent products in all areas impacting safety and effectiveness.

5.6 Conclusion

The Danyang K3/K4 lightweight wheelchair raises no safety and efficiency issues or makes any claims that differ from the predicate device cited.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 6 2009

Danyang Huayi Medical Supply & Equipment Company, Limited
% Mr. Jiuguang Song
Managing Director
China Solution Consulting
3119 Brick Lane
Decatur, Georgia 30033

Re: K091482
Trade/Device Name: Danyang Huayi K3/K4 Lightweight Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: I
Product Code: IOR
Dated: May 17, 2009
Received: May 19, 2009

Dear Mr. Song:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

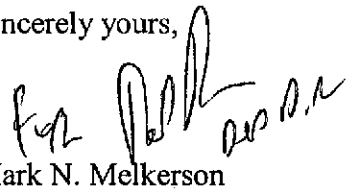
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091482

Device Name: Danyang Huayi K3/K4 lightweight wheelchair

Indications for Use:

The Danyang Huayi K3/K4 lightweight wheelchair is indicated for providing mobility to persons limited to a sitting position.

Prescription Use: Yes AND/OR Over-The-Counter Use___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091482